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October 1, 2009

VIA ELECTRONIC FILING AND FEDERAL EXPRESS

Honorable Freda L. Wolfson, U.S.D.J.
402 East State Street, Room 5050
Trenton, New Jersey 08608

Re: Novo Nordisk Inc., et al. v. Mylan Pharmaceuticals Inc.
Civil Action No. 09-2445 (FLW) (DEA),
Supplemental Authority in Support of *Defendants' Motion to Dismiss First Amended Complaint for Patent Infringement* (Dkt. No. 37)
(Return date October 5, 2009)

Dear Judge Wolfson:

We, along with our co-counsel at Perkins Coie, represent the defendant Mylan Pharmaceuticals Inc. ("Mylan") in the above-captioned matter.

Mylan writes to provide Your Honor supplemental authority in support of its *Motion to Dismiss First Amended Complaint for Patent Infringement* (Dkt. No. 37) ("Br.") and *Reply Brief in Support of Defendants' Motion to Dismiss First Amended Complaint for Patent Infringement* (Dkt. No. 45) ("Reply Br."), by respectfully submitting for Your Honor's consideration a decision issued September 24, 2009, by the Eastern District of Michigan in *Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, Case No. 05-40188, 2009 U.S. Dist. LEXIS 87895 ("Michigan decision") (attached hereto as Exhibit A), and its corresponding Order and Injunction, 2009 U.S. Dist. LEXIS 88551, issued September 25, 2009 (attached hereto as Exhibit B). Both were issued after the close of briefing on Mylan's pending motion to dismiss. Dkt. No. 45. The *Novo v. Caraco* action concerns the same patent, U.S. Patent No. 6,677,358 ("the '358 patent"), asserted by Novo against Mylan in this case.

Like Mylan, "Caraco seeks FDA approval only to market a generic version of repaglinide; it does not seek approval to market repaglinide in combination with metformin, the only use covered by claim 4 of the '358 patent." Exh. A at *3-*4.[1] As the Michigan court noted: "The '358 patent which is the subject of this patent action does not cover repaglinide; it covers repaglinide only in combination with metformin." *Id.* at *3. It was on this basis that Mylan filed a "section viii statement" certifying that its repaglinide ANDA does not claim a use which is covered by the '358 patent, rather than a paragraph IV certification, which is a prerequisite to this Court's jurisdiction under the Hatch-Waxman Act. *See* Br. at 1-2, 10-12; Reply Br. at 2.

Novo opposed Mylan's motion to dismiss by raising the novel argument that the Court has jurisdiction *if* Mylan's ANDA "should have contained a paragraph IV certification," whether or not it actually did. Opp.[2] at 10-13. In May 2009, after Mylan filed its ANDA, Novo amended its "use code" listing in the Orange Book for claim 4 of the '358 patent from the "use of repaglinide in combination with metformin to lower blood glucose" to the much broader "[a] method for improving glycemic control in adults with type 2 diabetes mellitus." Exh. A at *1 n.1; *id.* at *1-*2; Amended Complaint at ¶ 17. According to Novo, as a result of its amendment to the use code, the FDA will require Mylan to amend its ANDA to include a paragraph IV certification. *See* Opp. at 10-13; Amended Complaint at ¶¶ 23-26.

The September 24 ruling by the Eastern District of Michigan destroys the premise of this entire argument. The Michigan court has held that Novo's amended use code listing is much broader than the actual scope of the claims of the '358 patent and therefore should never have been filed with the FDA. Exh. A at *5-*7. Indeed, the Michigan court has issued an injunction requiring Novo to *withdraw* the amended use code and replace it with the *original* use code listing in the Orange Book. Exh. B at *2-*3. Novo does not and cannot dispute that Mylan's section viii certification was proper and legally appropriate with respect to the original use code, the use code Novo is now under a court order to reinstate. There is thus no factual basis for the FDA to "require" Mylan to file a paragraph IV certification going forward, and no legal basis for arguing that Mylan "should have" filed a paragraph IV certification in the first place. And, as Mylan has explained in its earlier briefs, it is black-letter law that without a paragraph IV

[1] Claim 4 covers a method for treating diabetes "comprising administering to a patient in need of such treatment repaglinide in combination with metformin" and is the only claim of the '358 patent asserted by Novo in its Amended Complaint. '358 patent, Dkt. No. 26-2 at col. 10, *ll.* 48-51; Br. at 1 n.1.

[2] "Opp." refers to *Novo Nordisk's Memorandum of Law in Opposition to Defendant's Motion to Dismiss First Amended Complaint for Patent Infringement* (Dkt. No. 41).

certification, this Court lacks jurisdiction over Novo's claim of direct infringement unless and until Mylan commits one of the acts of infringement specified in § 271(a).[3]

Sincerely,

/s/ Arnold B. Calmann

Arnold B. Calmann

Enclosures

cc: **(w/enc., via ECF & Federal Express)**
Hon. Douglas E. Arpert, U.S.M.J.

(w/enc., via ECF & email)
All counsel of record

[3] The second prong of Mylan's motion to dismiss, that Novo cannot allege indirect infringement without a predicate act of direct infringement, continues to be valid and is not affected by the Michigan court's recent ruling.

Supplemental Authority in Support of Defendants' Motion to Dismiss First Amended Complaint for Patent Infringement (Dkt. No. 37)

EXHIBIT A

NOVO NORDISK A/S and NOVO NORDISK, INC., Plaintiffs, -vs- CARACO PHARMACEUTICAL LABORATORIES, LTD. and SUN PHARMACEUTICAL INDUSTRIES, LTD., Defendants,

Case No. 05-40188

UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF MICHIGAN, SOUTHERN DIVISION

2009 U.S. Dist. LEXIS 87895

September 24, 2009, Decided
September 24, 2009, Filed

COUNSEL: [*1] For Novo Nordisk A/S, Plaintiff: Josh A. Krevitt, LEAD ATTORNEY, Gibson, Dunn, New York, NY; Michael A. Sitzman, Gibson, Dunn & Crutcher LLP, San Francisco, CA; Michelle L. Alamo, Dickinson Wright, Detroit, MI.

For Novo Nordisk, Incorporated, Plaintiff: Josh A. Krevit, LEAD ATTORNEY, Gibson, Dunn, New York, NY; Michelle L. Alamo, LEAD ATTORNEY, Dickinson Wright, Detroit, MI; Michael A. Sitzman, Gibson, Dunn & Crutcher LLP, San Francisco, CA.

For Caraco Pharmaceutical Laboratories, Limited, Sun Pharmaceutical Industries, Limited, Defendants: Charles B. Klein, Winston & Strawn, Washington, DC; David S. Bloch, Winston and Strawn, San Francisco, CA; Morley Witus, Barris, Sott, Detroit, MI.

For Grauer, Interested Party: Richard D. Grauer, LEAD ATTORNEY, Huntington Woods, MI.

For Caraco Pharmaceutical Laboratories, Limited, Sun Pharmaceutical Industries, Limited, Counter Claimants: David S. Bloch, Winston and Strawn, San Francisco, CA; Morley Witus, Barris, Sott, Detroit, MI.

For Novo Nordisk A/S, Novo Nordisk, Incorporated, Novo Nordisk A/S, Novo Nordisk, Incorporated, Novo Nordisk A/S, Novo Nordisk, Incorporated, Counter Defendants: Michelle L. Alamo, LEAD ATTORNEY, Dickinson Wright, Detroit, [*2] MI; Josh A. Krevitt, Gibson, Dunn, New York, NY; Michael A. Sitzman, Gibson, Dunn & Crutcher LLP, San Francisco, CA.

For Caraco Pharmaceutical Laboratories, Limited, Counter Claimant: Morley Witus, Barris, Sott, Detroit, MI.

JUDGES: Hon: Avern Cohn, United States District Court Judge.

OPINION BY: Avern Cohn

OPINION

DECISION RE: DOC. 318

This is a patent case involving the drug repaglinide marketed by Novo Nordisk (Novo) under the trade name Prandin. Now before the Court is Caraco Pharmaceutical Laboratories' (Caraco) Motion for Summary Judgment on Count IV of Its Third Amended Counterclaim and Sixth Affirmative Defense for Patent Misuse (Dkt. 318). The background of the case as well as Caraco's motion is described in the Court's decisions reported at *450 F. Supp. 2d 757 (E.D. Mich. 2006)* (finding allegations of complainant sufficient to state a claim against Sun) and *2009 U.S. Dist. LEXIS 77856, 2009 WL 2768955 (E.D. Mich. Aug. 31, 2009)* (holding that Caraco can challenge an alleged incorrect use code narrative and the Hatch-Waxman Act allows for the affirmative defense of patent misuse in such circumstances).

For the reasons which follow, the Court finds that Novo has improperly filed with the FDA for listing in the Orange Book the use code narrative [*3] for the method of use of claim 4 of the *'368 patent* relating to Prandin, and Caraco is entitled to a mandatory injunction requiring Novo to request the FDA to delist the U-968 listing for Prandin, and reinstate its former U-546 listing for Prandin. Novo's defense to Caraco's motion is a farrago of misstated and irrelevant facts and misstated law.

Novo's patent on repaglinide, RE37,035, expired on March 14, 2009. Caraco's ANDA covers repaglinide. The *'358 patent* which is the subject of this patent action does not cover repaglinide; it covers repaglinide only in combination with metformin. The U-968 use code narrative for the *'358 patent* states "a method for improving

glycemic control in adults with type 2 diabetes mellitus." It is so broad as to incorrectly suggest that the *'358 patent* generically covers three (3) different FDA-approved methods of use of repaglinide:

. monotherapy treatment

. treatment in combination with thiazolidinediones

. treatment in combination with metformin

However, Novo admits that the first two (2) uses are not covered by claim 4 of the *'358 patent*. Caraco seeks FDA approval only to market a generic version of repaglinide; it does not seek approval to market repaglinide [*4] in combination with metformin, the only use covered by claim 4 of the *'358 patent*.

Novo filed the new U-968 use code on May 6, 2009, shortly after the *'035 patent* expired, as a significantly broadened replacement for use code U-546 that it previously submitted for the *'358 patent*. [1] As a result of the revised use code, the FDA will no longer permit Caraco to file a "section viii statement" carving out the patented repaglinide-metformin combination therapy as a predicate for securing approval of Caraco's ANDA to market its generic repaglinide for non-infringing uses.

1 U-546 specified "use of repaglinide in combination with metformin to lower blood glucose."

Because the FDA does not review use code narratives as explained in the August 31, 2009, decision, it has required Caraco as part of its ANDA to "submit an updated patent certification addressing the 6,677,358 patent and its associated Use Code 968." Fax from William Peter Rickman, Director of the Division of Labeling and Program Support, FDA, to Veeranna Lolla, Caraco Pharmaceutical Laboratories (Aug. 3, 2009). Caraco has therefore been seriously disadvantaged by the improper U-968 use code narrative.

Novo acknowledges that monotherapeutic [*5] use of repaglinide is not covered by the *'358 patent*: "[T]he *'358 patent* contains 5 claims one of which (claim 4) is directed to a method of treatment of NIDDM with a combination of repaglinide and metformin." Letter from Rosemarie R. Wilk-Orescan, Senior Counsel, Novo Nordisk, to the FDA (June 9, 2008).

This limitation is reiterated in the Novo's Amended Complaint: "In the *'358 patent* claim. . .a method for treating NIDDU by administering to a patient in need of treatment repaglinide in combination with metformin (claim 4)." Amended Complaint at P 10, Novo Nordisk v. Caraco Pharmaceutical Laboratories, No. 05-40188 (E.D. Mich. Sept. 14, 2005). The Orange Book listing of Prandin reads:

*2*Proprietary Name	*3*PRANDIN			
Patent Data				
Appl. No.	Prod. No.	Patent No.	Patent Expiration	Patent Use Code
020741	001	*6,677,358*	06/12/2018	U-968 [2]
020741	001	*RE37,035*	03/14/2009	

2 Patent Use Code U-968: A method for improving glycemic control in adults with type 2 diabetes mellitus.

The FDA has made clear that a use code description must be "accurate and detailed." *68 Fed. Reg. 36,682 (June 18, 2003)*.

FDA regulations state that the use code must properly describe in sufficient detail the scope of the patented method covering [*6] an approved use of the referenced drug. *21 C.F.R. § 314.53(c)(2)(ii)*. The Patent Information submitted by Novo on its May 6, 2009 Form FDA 3542 for Prandin did not comply with the applicable FDA regulations and instructions, resulting in the U-968 use code that seriously misrepresents the approved method of use covered by claim 4. The Memorandum of August 31, 2009 summarized the clear legislative intent behind the 2003 amendments to Hatch-Waxman that added the counterclaim provision, *§ 355(j)(5)(C)(ii)*, namely, to curb Orange Book abuses arising from misinformation regarding listed patents. As provided for by the statute Caraco is entitled to "an order requiring

[Novo] to correct . . . the patent information submitted" to the FDA in Form 3542. *21 U.S.C. § 355(j)(5)(C)(ii).*

Caraco is correct when it says:

> Novo . . . asserts . . . that the following accurately and completely describes the scope of the *'358 patent*'s method claim: "a method for improving glycemic control in adults with Type 2 diabetes mellitus." This new use code is . . . vague on its face because it does not provide, as [the regulations] require[ ], "[t]he description of the patented method of use" in a manner that is both [*7] "accurate and detailed." *21 C.F.R. § 314.53(c)(2)(ii)(P); 68 Fed. Reg. at 36682.* On the contrary, this. . .use code fails to identify with any specificity whatsoever the patented method and, read literally, suggests that [the *'358] patent* covers any method of improving glycemic control in adults with Type 2 diabetes mellitus. [One cannot] tell from this use code description alone which of the three repaglinide uses purportedly falls within the scope of the *'358 patent.*

Brief of Caraco Pharmaceutical Laboratories at 10, Novo Nordisk v. Caraco Pharmaceutical Laboratories, No. 05-40188 (E.D. Mich. June 19, 2009).

Lastly, Novo proposed the new use code narrative not to more accurately describe the method of use of Prandin covered by claim 4 of the *'358 patent*, but "as part of its longstanding efforts to ensure that information about the predominant approved use of repaglinide -- *i.e.*, in combination therapy with metformin -- is provided to repaglinide consumers." Brief of Novo Nordisk. at 25, Novo Nordisk v. Caraco Pharmaceutical Laboratories, No. 05-40188 (E.D. Mich. Sept. 10, 2009).

Novo is not a private FDA. Novo, by the change in the use code narrative is attempting to extend the life [*8] of an expired patent. The FDA is fully equipped to ensure that the label for Caraco's generic version of repaglinide is adequate to inform the public.

Caraco shall submit an order implementing this decision on notice to Novo.

Dated: September 24, 2009

/s/ Avern Cohn

U.S. District Court Judge

Supplemental Authority in Support of Defendants' Motion to Dismiss First Amended Complaint for Patent Infringement (Dkt. No. 37)

EXHIBIT B

NOVO NORDISK A/S and NOVO NORDISK INC., Plaintiffs-Counterclaim Defendants, v. CARACO PHARMACEUTICAL LABORATORIES, LTD. and SUN PHARMACEUTICAL INDUSTRIES, LTD., Defendants-Counterclaim Plaintiffs.

Civil Action No. 2:05 CV 40188

UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF MICHIGAN

2009 U.S. Dist. LEXIS 88551

September 25, 2009, Decided
September 25, 2009, Filed

COUNSEL: [*1] For Novo Nordisk A/S, Plaintiff: Josh A. Krevitt, LEAD ATTORNEY, Gibson, Dunn, New York, NY; Michael A. Sitzman, Gibson, Dunn & Crutcher LLP, San Francisco, CA; Michelle L. Alamo, Dickinson Wright, Detroit, MI.

For Novo Nordisk, Incorporated, Plaintiff: Josh A. Krevitt, LEAD ATTORNEY, Gibson, Dunn, New York, NY; Michelle L. Alamo, LEAD ATTORNEY, Dickinson Wright, Detroit, MI; Michael A. Sitzman, Gibson, Dunn & Crutcher LLP, San Francisco, CA.

For Caraco Pharmaceutical Laboratories, Limited, Sun Pharmaceutical Industries, Limited, Defendants: Charles B. Klein, Winston & Strawn, Washington, DC; David S. Bloch, Winston and Strawn, San Francisco, CA; Morley Witus, Barris, Sott, Detroit, MI.

For Grauer, Interested Party: Richard D. Grauer, LEAD ATTORNEY, Huntington Woods, MI.

For Caraco Pharmaceutical Laboratories, Limited, Sun Pharmaceutical Industries, Limited, Counter Claimants: David S. Bloch, Winston and Strawn, San Francisco, CA; Morley Witus, Barris, Sott, Detroit, MI.

For Novo Nordisk A/S, Novo Nordisk, Incorporated, Counter Defendants: Michelle L. Alamo, LEAD ATTORNEY, Dickinson Wright, Detroit, MI; Josh A. Krevitt, Gibson, Dunn, New York, NY; Michael A. Sitzman, Gibson, Dunn & Crutcher [*2] LLP, San Francisco, CA.

For Caraco Pharmaceutical Laboratories, Limited, Counter Claimant: Morley Witus, Barris, Sott, Detroit, MI.

For Novo Nordisk A/S, Novo Nordisk, Incorporated, Counter Defendants: Josh A. Krevitt, LEAD ATTORNEY, Gibson, Dunn, New York, NY; Michelle L. Alamo, LEAD ATTORNEY, Dickinson Wright, Detroit, MI; Michael A. Sitzman, Gibson, Dunn & Crutcher LLP, San Francisco, CA.

JUDGES: AVERN COHN, United States District Judge.

OPINION BY: AVERN COHN

OPINION

ORDER AND INJUNCTION

The Court has granted Caraco's Motion for Summary Judgment on its Fourth Counterclaim and Sixth Affirmative Defense (Dkt # 317), with regard to Caraco's Fourth Counterclaim asserted under *21 U.S.C. § 355(j)(5)(C)(ii)(I)(bb)*, as set forth in the Court's Decision re: Doc. 318 (Dkt # 421). The Court previously denied Novo Nordisk's Motion to Dismiss (Dkt # 337) in a Memorandum decision (Dkt # 371). In accordance with those two decisions, the Court hereby enters the following Injunction:

Novo Nordisk is hereby directed by mandatory injunction under *21 U.S.C. § 355(j)(5)(C)(ii)(1)(bb)* to correct within twenty (20) days from the date of this Order and Injunction its inaccurate description of the *'358 patent* by submitting to FDA an amended [*3] Form FDA 3542 that reinstates its former U-546 listing for Prandin and describes claim 4 of the *'358 patent* in section 4.2b as covering the "use of repaglinide in combination with metformin to lower blood glucose."

SO ORDERED this 25th day of September, 2009

/s/ Avern Cohn

AVERN COHN

United States District Judge